Systematic literature review of the efficacy and safety of infigratinib for the treatment of advanced cholangiocarcinoma

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Background and objectives

- Patients with advanced cholangiocarcinoma (CCA) have limited treatment options.[1]
- Fibroblast growth factor receptor (FGFR) fusions are found in 10-16% of patients with CCA.[2]
- Infigratinib is a selective FGFR2 inhibitor.
- The aim of this study was to evaluate the efficacy and safety of infigratinib for the treatment of advanced CCA.

Methodology

- **SEARCH STRATEGY**: PubMed, Embase®, and Cochrane via Ovid platform were searched on 11th October 2021 for studies reporting safety and efficacy of infigratinib in patients with advanced CCA.
- No restriction regarding year of publication was applied.
- Two reviewers independently searched for articles and extracted data, with differences resolved through consensus.
- **SELECTION CRITERIA**: Inclusion of articles was based on the following PICOS criteria:
  - **POPULATION**: Adults (≥18 years old) with advanced CCA
  - **INTERVENTION**: Infigratinib
  - **OUTCOMES**: Overall survival (OS), progression-free survival (PFS), disease free survival, overall response rate (ORR) disease control rate, duration of response, time to response, time to progression, safety and quality of life
  - **STUDY DESIGN**: Clinical trials (any phase), cohort study (retrospective or prospective), observational study (retrospective or prospective), case-control study

Results

- Of 166 identified studies, only two studies satisfied our inclusion criteria (Figure 1).
- Both were Phase II, single-arm studies with 125 mg of oral infigratinib once daily for 21 days of 28-day cycle.
- In Javle et al. 2021, treatment with infigratinib resulted in an ORR of 23.1% (95% confidence interval [CI] 15.6-32.2), a complete response rate of 1%, and a partial response rate of 22%.
- The median PFS with infigratinib was 7.3 months (95% CI 5.6-7.6), while PFS rates at 6 and 12 months was 56.49% and 16.88%, respectively (Figure 2).
- The median OS with infigratinib was 12.2 months (95% CI 10.7-14.9), while OS rates at 6, 12, 24 months were 87.4%, 50.5%, 27.1% respectively (Figure 3).
- Grade 3 and grade 4 adverse events were reported in 56.0% and 8.0% of patients respectively (Figure 4).
- No treatment-related deaths were observed.
- Goyal et al. 2019, reported a mean PFS of 8.4 months.

Figure 1: PRISMA diagram

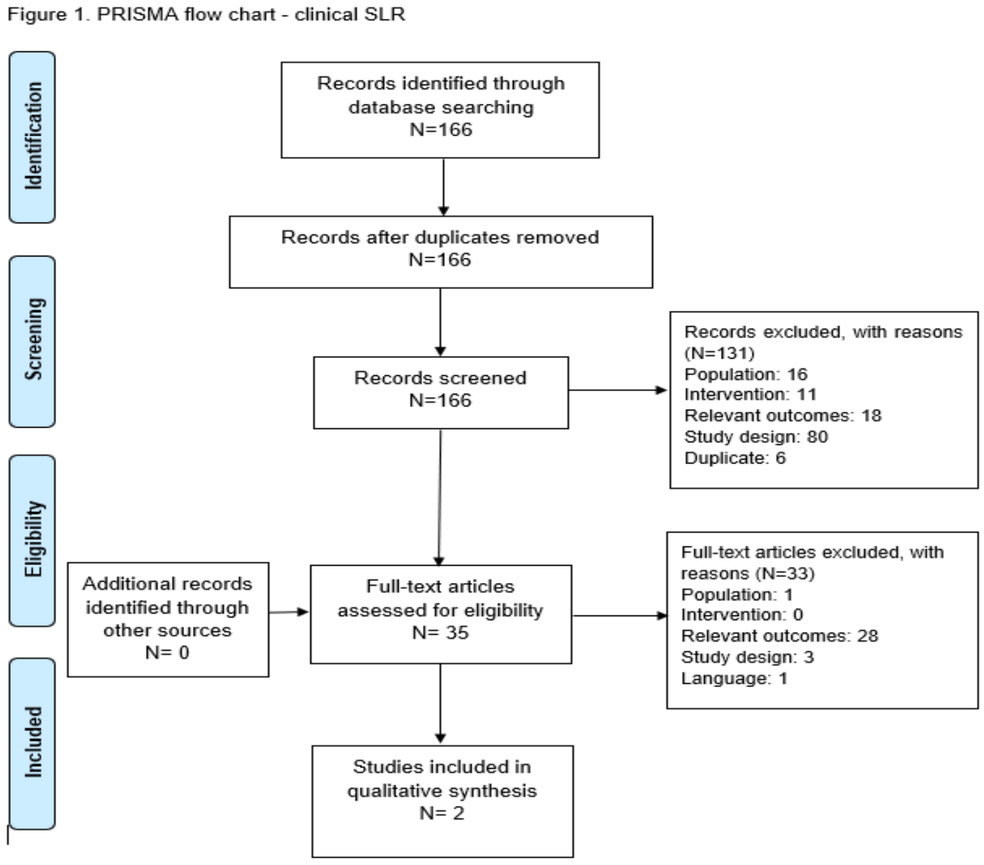


Figure 2: Progression-free survival with infigratinib

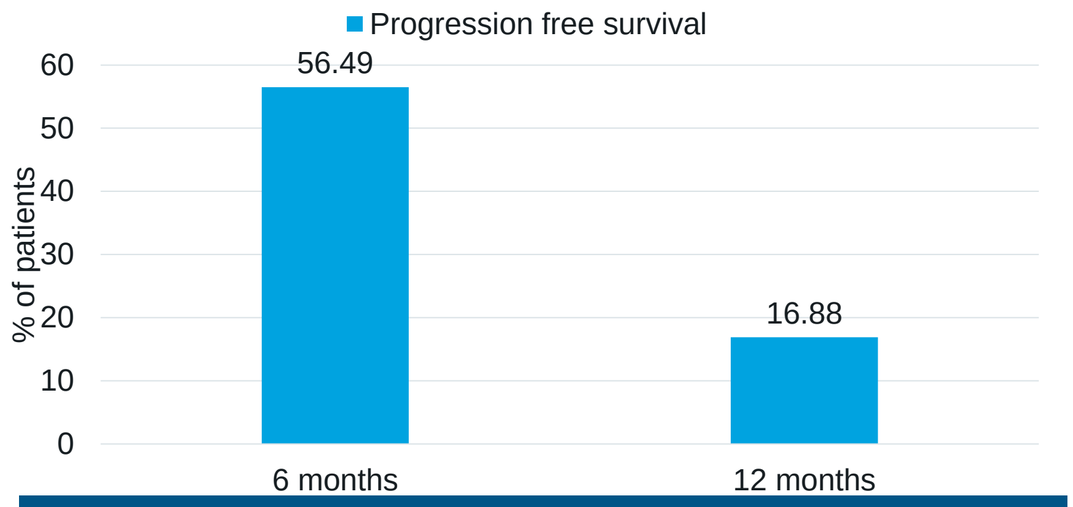


Figure 3: Overall survival with infigratinib

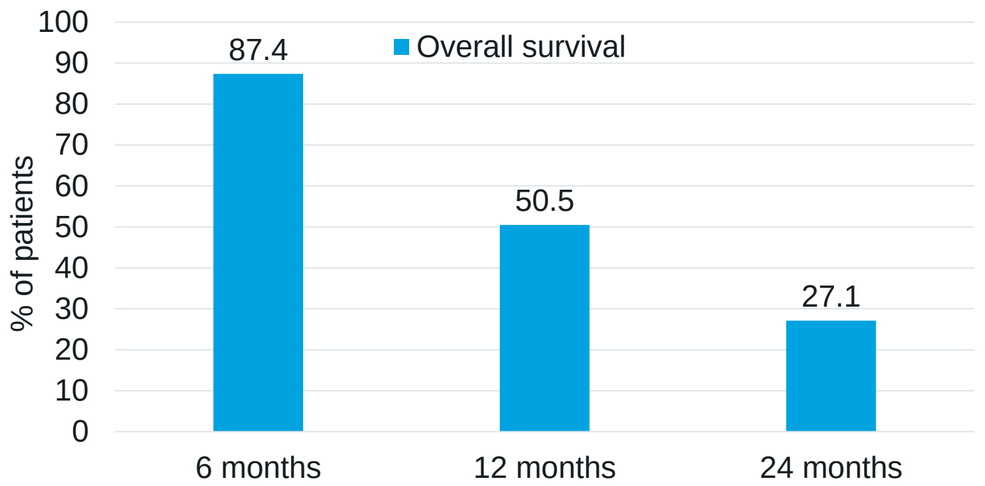
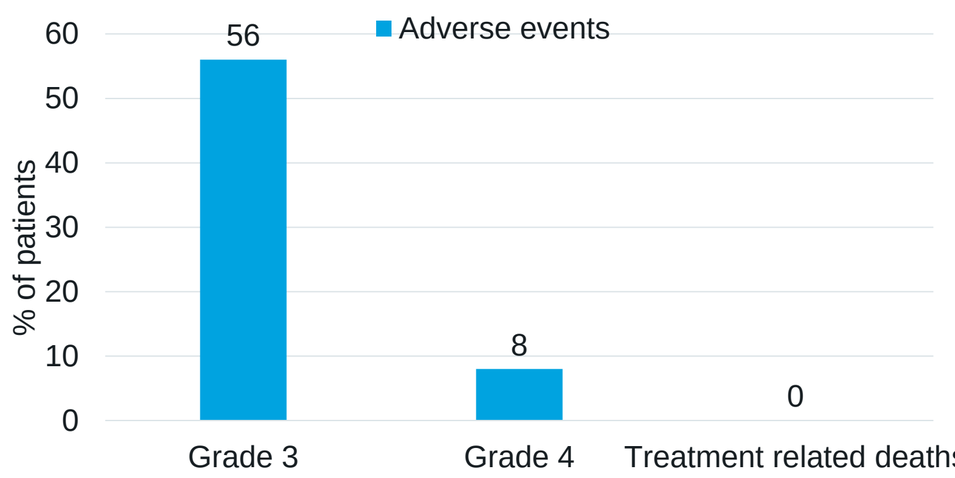


Figure 4: Adverse events



Conclusion

- Infigratinib demonstrated good therapeutic activity and a fair safety profile in locally advanced or metastatic CCA.
- Further studies are needed to ascertain the therapeutic benefit of infigratinib in CCA.
- PROOF 301, a phase III multicenter, open label, randomized trial of infigratinib versus standard of care in advanced/metastatic CCA is ongoing.

Source: 1) Alqahtani SA, Colombo M. Systemic therapy for advanced cholangiocarcinoma: new options on the horizon. Hepatoma Research. 2020 Oct 12;6:70. 2) Abou-Alfa GK, Sahai V, Hollebecque A, Vaccaro G, Melisi D, Al-Rajabi R, Paulson AS, Borad MJ, Gallinson D, Murphy AG, Oh DY. Pemigatinib for previously treated, locally advanced or metastatic cholangiocarcinoma: a multicentre, open-label, phase 2 study. The Lancet Oncology. 2020 May 1;21(5):671-84.

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